USSN: 09/466,035 Dkt. No.: PP01231.105

2300-1231.01

#### **REMARKS**

#### STATUS OF THE CLAIMS

Claims 1-5, 12, 13, 24 and 25-30 were pending and were variously rejected under 35 U.S.C. §§ 102 and 103. Claim 1 has been amended as shown above to make explicit that the gene delivery vehicle and protein are not administered as a mixture or complex. Support of this amendment can be found throughout the specification as filed, for example on page 3, lines 31-34. Thus, claims 1-5, 12, 13, 24 and 25-30 are pending as shown above.

## **INFORMATION DISCLOSURE STATEMENT**

Submitted herewith is an Information Disclosure Statement in order to disclose copending application U.S. Serial No. 08/878,373. Applicants also direct the Examiner's attention to the prosecution history of this application.

## 35 U.S.C. § 102(E)

Claims 1-5, 24 and 26-30 stand rejected as allegedly anticipated by U.S. Patent No. 6,689,757 (hereinafter "Craig" et al.).

Claim 1 has been amended above to make explicit that the gene delivery vehicle and peptide are not delivered concurrently as a mixture or complex. Since Craig is limited entirely to co-administration of a mixture or complex comprising both a gene delivery vehicle and a protein, this reference does not teach or suggest all of the claimed elements. In this regard, the Office's interpretation that "the antigen component of the mixture administered prior to administration of the gene delivery vehicle" is incorrect. *See*, Final Office Action, sentence bridging pages 3-4, citing column 24, lines 35-42 of Craig. Indeed, Craig clearly and unambiguously indicates that the "complexes and mixtures of the invention" as referred to at column 24, lines 35-42 necessarily include both polynucleotide and polypeptide components:

The present invention provides methods and compositions for obtaining long-lasting immunity via delivery to an antigen presenting cell a complex comprising a nucleic acid encoding a first epitope, and a peptide containing a second epitope. column 1, lines 61-65 of Craig.

The invention therefore encompasses a method of vaccinating a mammal against a disease, comprising administering to said mammal a mixture of (i) a nucleic acid encoding a first epitope and (ii) a peptide comprising a second epitope such that the nucleic acid and the peptide are taken up by and the nucleic acid is expressed in a professional antigen presenting cell of the mammal, wherein an immune response is elicited in the mammal to the epitopes. column 2, lines 16-23 of Craig.

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Thus, unlike the claimed subject matter in which polynucleotides and polypeptides are administered separately, Craig relates entirely to single or multiple administrations of complexes or mixtures including both polynucleotides and polypeptides. Accordingly, this reference cannot anticipate the claimed methods and Applicant respectfully submit that this rejection should be withdrawn.

# 35 U.S.C. § 103(A)

Claims 1, 12 and 13 were rejected as allegedly obvious over Craig in view of U.S. Patent No. 5,843,723 (hereinafter "Dubensky"). Craig is cited as above and Dubensky is cited for teaching alphavirus and eukaryotic layered vector initiation system vectors. Final Office Action, pages 4-5.

For the reasons detailed above, Craig fails to describe or suggest methods in which gene delivery vehicles and proteins are administered separately, as set forth in the claims. Dubensky also fails to teach such methods. Therefore, there is no combination of Craig and Dubensky that would lead one of skill in the art to the claimed subject matter and withdrawal of this rejection is respectfully requested.

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## **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

Please direct all further communications regarding this application to:

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